DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
Facsimile: 615-781-5391

January 7, 2005

Warning Letter No. 2005-NOL-09

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Peter Schiff, Owner
Peter Schiff Enterprises
4900 Forrest Hill Road
Cookeville, Tennessee 38506

Dear Mr. Schiff:

On November 16-17, 2004, an investigator from the Food and Drug Administration (FDA) conducted an inspection of your facility, Peter Schiff Enterprises, 4900 Forrest Hill Road, Cookeville, Tennessee 38506. This inspection determined your firm to manufacture adult and pediatric size cardiac electrode pads and AC fibrillators. These products are medical devices under the Federal Food, Drug, and Cosmetic Act (the Act), because they are intended for use in diagnosing or treating a medical condition or to affect the structure or a function of the body (Section 201(h) of the Act). You can find the Act and the *Code of Federal Regulations* (CFR) through links in FDA's home page at http://www.fda.gov.

The above-stated inspection revealed the devices to be adulterated within the meaning of Section 501(h) of the Act [21 USC 351(h)] in that the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation, as specified in 21 CFR 820. Specific QS violations include:

1. Failure to conduct quality audits by an individual not having direct responsibility for matters being audited to verify the quality system is effective in fulfilling your quality system objectives, as required by 21 CFR 820.22. Specifically, you stated during the inspection your inability to afford an outside auditor to perform quality audits and the conduct of audits is not necessary.

2. The device history records fail to demonstrate the device is manufactured in accordance with the device master record, as required by 21 CFR 820.184. Specifically, device history records fail to include acceptance records of the incoming components and oscilloscope testing of finished fibrillators.

3. Failure to verify, validate, and document changes to specifications, specifically for the fibrillator, as required by 820.70(b). Specifically, service records involved a male connection breaking off from the terminal post. The male connectors were replaced with female connectors to prevent the problem. You failed to have any type of documentation of the design change or evidence to verify the change did not adversely affect the device.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by FDA. You also must promptly initiate permanent corrective and preventive action on your QS.

Federal agencies are advised of the issuance of all warning letters about devices so they may take this information into account when considering the award of contracts. Additionally, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, which may include, but are not limited to seizures, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure similar violations will not recur.

If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be directed to the attention of Kimberly L. McMillan, Compliance Officer, 297 Plus Park Boulevard, Nashville, TN 37217. If you have any questions concerning the violations noted, please contact Ms. McMillan at (615) 781-5380 extension 138.

Sincerely,

H. Tyler Thornburg
Director, New Orleans District

KLM/klm

Enclosure: FDA 483 & 21 CFR 820